

CLAIMS

1. An assay method for drug metabolizing activity of UDP-glucuronosyltransferase (UGT), comprising a step of detecting (a) mutation(s) in an exon 5 region of a gene coding
5 for UGT.
2. The assay method according to claim 1, further comprising a step of detecting (a) mutation(s) of an increase or decrease in the repeating sequence of TA present in a TATA box of
10 a promoter region.
3. The assay method according to claim 1 or 2, wherein the method comprises a step of detecting (a) mutation(s) in an exon 5 region having a nucleotide sequence that is common
15 to each isoform of UGT1A1, UGT1A3, UGT1A4, UGT1A5, UGT1A6, UGT1A7, UGT1A8, UGT1A9 and UGT1A10 for a sample including a gene coding for UGT1, without conducting an assay for each of the isoforms.
- 20 4. The assay method according to claim 3, comprising a step of detecting (a) mutation(s) in the exon 5 region of each isoform of UGT1A molecule, that correspond(s) to nucleotide number 1456 in the genetic sequence of UGT which encodes an amino acid at position 486 in the amino acid sequence
25 of UGT1A1 molecule.

5. The assay method according to any one of claims 1 to 4, comprising, in addition to the step of detecting the mutation(s), a step of detecting (a) mutation(s) in at least one region of the regions of exons 1, 2, 3, and 4 of a genetic sequence coding for a UGT molecule.

6. The assay method according to claim 5, comprising a step of detecting at least one genetic sequence mutation of a mutation at nucleotide number 226 in a genetic sequence of UGT coding for an amino acid at position 71 in the amino acid sequence of UGT1A1 molecule and a mutation at nucleotide number 486 in a genetic sequence coding for an amino acid at position 229 in the amino acid sequence of UGT1A1 molecule.

7. A UGT gene having (a) mutation(s) comprising the base substitution described in claim 3 or 4, or a gene fragment including the mutation(s).

8. DNA fragments having a functionally effective length as assayed DNA that are provided for the detection method for a base substitution described in any one of claims 1 to 6, or DNA fragments having a functionally effective length as probes for use in the detection method for a base substitution described in any one of claims 1 to 6.

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9. The DNA fragments according to claim 7 or 8, which are

oligonucleotide probes that are specific to UGT having a base sequence set forth in any one of SEQ ID NOS: 1 to 3.

10. The assay method according to claim 5 or 6, which uses
5 a combination of probes having a base sequence set forth in SEQ ID NO: 1 and probes having a base sequence set forth in SEQ ID NO: 2 and/or 3.

11. A detection device in which the oligonucleotide probes
10 according to any one of claims 7 to 9 or the oligonucleotide probes used for the method according to claim 10 are provided within the same device.

12. The detection device according to claim 11, which is
15 a nucleic acid array or a nucleic acid chip in which an end of the base sequence of the oligonucleotide probes according to any one of claims 7 to 9 is immobilized by bonding to an insoluble support via a functional group.

20 13. A method for assessing, predicting or assaying drug metabolism using the device according to claim 11 or 12.

14. An assay kit used in the method according to any one of claims 1 to 6, 10 and 13, which includes the nucleic acid
25 fragments according to any one of claims 7 to 9 or the device according to claim 11 or 12.